REMARKS

Substance of Telephone Interview

Applicants gratefully acknowledge the Examiner's attempt to ensure Applicants receive the first Office Action and are given time to respond by establishing a new mailing date of October 27, 2003.

Applicants contacted the Examiner first on August 7th, 2003, and finally on October 6, 2003 regarding Applicants' failure to receive the first Office Action (apparently mailed March 12, 2003, as reported in the PAIR system). The Examiner responded by sending the Office Action with the new mailing date of October 27, 2003 and having a shortened statutory time for response set to expire on January 17, 2003. This amendment is intended to respond to this Office Action.

Status of the Claims

Claims 1-14 are pending.

Claims 1-14 are rejected under 35 U.S.C. § 103.

Amendments

In order to clarify the nature of the invention, Claim 1 has been amended to incorporate the limitations of Claim 13 ("further including cardioprotective minerals and vitamins"). Applicants believe that no new matter has been added thereby and that the scope of the claims is not broadened.

Section 103 Rejections

The Examiner has rejected claims 1-14 under 35 U.S.C. 103(a) as being unpatentable over US Pat. #6,0340,645 ("Tritsch et al.) in view of US Pat #5,925,381 ("Boyle et al."), EP 0595005 and US Pat. # 4,486,435 ("Schmidt et al."). The Examiner contends that the only difference between the prior art and the claimed invention is that the prior art does not expressly disclose a composition or method of providing a cardiovascular benefit containing in combination encapsulated vitamin E, precipitated silica, calcium silicate, MCC and, optionally talc. Examiner generally alleges that "the prior art amply suggests Applicants' composition "as it is known in the art to formulate mixtures of vitamin, including Vitamin E, and minerals in the form of tablets or coated tablets for the reduction of homocysteine levels." Finally, the Examiner contends that the preparation of tablets containing Applicants' claimed composition in the "various ratios and compositions" would have been obvious to one of skill in the art, and that the prior art provides motivation that the "lubricants and fillers

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would facilitate processing of the tablet and that such tablets would be effective in lowering homocysteine levels and provide a cardiovascular benefit. Applicants respectfully traverse.

As stated in the Specification, page 15, lines 4-9, "[t]he incorporation of a high concentration of Vitamin E in a composition adapted for compression into tablets or caplets presents many difficulties. Primarily, during compression and/or over time the Vitamin E oil leaches out of the Vitamin E beadlets, or spray dried Vitamin E, into the tablet matrix, resulting in loss of tablet integrity and/or undesirable change in the tablets' dissolution rate." This is especially true of Applicants' compositions additionally containing vitamins and minerals as mineral mixtures are not easily compressible and generally require high compression forces to produce acceptable tablets.

Applicants have discovered that tablets and caplets having high Vitamin E content that further contains cardioprotective minerals and vitamins that are formed in accordance with the presently claimed "ratios and concentrations" have surprising stability. A stable tablet is defined to be a tablet that is stored at room temperature for a period of at least twelve months from the date of manufacture of the tablet or one that stored for three months at 40 C and 75% relative humidity in which encapsulated Vitamin E has not leached out into the matrix of the tablet (see Specification, page 15, lines 13-18). Please find appended to this amendment a table prepared by the inventor, Atef Boulos in which data (data also presented in earlier declaration by inventor Neil Martin) is presented illustrating the criticality of the claimed ratios and concentrations of the various components of Applicants' composition to the manufacture of a stable tablet.

None of the references cited by the Examiner address the production of a stable vitamin and/or mineral-containing tablet, nor do they suggest or provide motivation to achieve such a stable tablet. Rather, the powders described by Tritsch, Boyle, EP 0595005 and Schmidt all merely teach raw powders containing vitamin E that have improved flow that may generally be used to form tablets by methods known in the art.

Only Tritsch actually exemplifies tablets containing the raw Vitamin E formulation, and only one example (Example #6 – corresponding to 210 IU per unit dose or 280 mg in a 75% formulation), contains over 100 IU of Vitamin E per unit dose. (The other two Tritsch examples containing Vitamin E in a tablet contain well under 100 IU/unit dose (See Example 7 and 8, each